[PUBLISH]

# In the

# United States Court of Appeals

For the Eleventh Circuit

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No. 23-11535

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In Re: DEEPWATER HORIZON BELO CASES,

BELO PLAINTIFFS,

Plaintiffs,

LESTER JENKINS, DWIGHT SIPLES,

Interested Parties-Appellants,

versus

BP EXPLORATION & PRODUCTION, INC., BP AMERICA PRODUCTION COMPANY,

Defendants-Appellees.

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| DWIGHT SIPLES,                        | JR.,   |                      |  |  |
|                                       |  | Plaintiff-Appellant, |  |  |
| LESTER JENKINS,                       |  |                      |  |  |
|                                       | Interes  | ted Party-Appellant, |  |  |
| versus                                |  |                      |  |  |
| BP EXPLORATION & PRODUCTION, INC.,    |  |                      |  |  |
| BP AMERICA PRO                        | DUCTION COMPANY,   |                      |  |  |
|                                       | De   | efendants-Appellees. |  |  |
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Before WILLIAM PRYOR, Chief Judge, and LUCK and ED CARNES, Circuit Judges.

WILLIAM PRYOR, Chief Judge:

This appeal asks whether the district court abused its discretion when it excluded expert opinion testimony about general causation in a suit related to the Deepwater Horizon oil spill. Lester Jenkins and Dwight Siples Jr. participated in the cleanup of that spill. And both men complain that their exposure to crude oil and dispersants during the cleanup caused chronic sinusitis. Because neither crude oil nor dispersants are known toxins, Jenkins and Siples needed to prove general causation. Their expert witnesses opined that a causal relationship existed between the cleanup work and chronic sinusitis. But the district court ruled that neither expert identified a minimal level of exposure at which crude oil, its dispersants, or the chemicals associated with either are hazardous to human beings. And it found that the experts failed to identify a statistically significant association between the chronic conditions and exposure to crude oil, assess various studies' limitations, or meaningfully consider causal factors. Because the district court did not abuse its discretion, we affirm the summary judgment against Jenkins and Siples.

#### I. BACKGROUND

This appeal rises and falls on the admission of expert evidence and the scientific methodologies that ground toxic-tort actions. So we begin with a short primer on those methods and the

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burdens of proof relevant to these suits. Then we turn to the facts and procedural history for this appeal.

#### A. A Primer on Toxic Torts

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Toxic-tort actions come in two forms. In the first, the medical community already recognizes that a specific "agent"—i.e., a substance external to the human body (think drugs, chemicals, minerals)—is toxic and capable of "caus[ing] the type of harm a plaintiff alleges." *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1239 (11th Cir. 2005). In these actions, the parties battle over specific causation only: that is, whether the agent caused a specific plaintiff's disease. *Id.* In the second, the medical community does not recognize an agent as both toxic and capable of causing the kind of injury a plaintiff alleges. *Id.* Plaintiffs in these actions must establish both general and specific causation.

General causation asks "whether an agent increases the incidence of disease in a group and not whether the agent caused any given individual's disease." Michael D. Green et al., *Reference Guide on Epidemiology*, in Reference Manual on Scientific Evidence 549, 623 (Fed. Jud. Ctr., 3d ed. 2011). In toxic-tort actions, plaintiffs prove general causation through epidemiological evidence, doseresponse relationship, and background risk of disease. *Chapman v. Procter & Gamble Distrib.*, *LLC*, 766 F.3d 1296, 1308 (11th Cir. 2014). Because these three kinds of evidence underpin our general-causation precedent, we describe each briefly.

*Epidemiology.* Epidemiology "studies the incidence, distribution, and [cause] of disease in human populations." Green, *supra*, at

551. Experts who rely on epidemiological evidence to establish general causation assess that evidence in two steps. To start, they ask whether the evidence "reveal[s] an association between an agent and [a] disease." *Id.* at 554. To identify an association, experts must rule out alternative explanations, by asking, for example, whether a potential association resulted from limitations in the study, like chance or bias. *Id.* at 554, 572. Experts also ask "whether the association reflects a true cause-effect relationship." *Id.* at 554, 597. In this context, causation means something akin to but-for cause: exposure to a toxic agent is "a necessary link in [the] chain of events" that led to the disease. *Id.* at 597–98.

To decide whether a particular study supports a causal inference, experts consider the nine factors developed by Sir Austin Bradford Hill: (1) temporal relationship; (2) strength of the association; (3) dose-response relationship; (4) replication of the findings; (5) biological plausibility; (6) consideration of alternative explanations; (7) cessation of exposure; (8) specificity of the association; and (9) consistency with other knowledge. *Id.* at 600 (citing Austin Bradford Hill, *The Environment and Disease: Association or Causation?*, 58 Proc. Royal Soc'y Med. 295, 295–300 (1965)). No factor is dispositive. And "[n]o algorithm exists for applying the Hill guidelines." *Restatement (Third) of Torts: Liability for Physical and Emotional Harm* § 28 cmt. c(3) (Am. L. Inst. 2010). Instead, their application requires judgment. *Id.* 

Dose-Response Relationship. At a high level, "a dose-response relationship means the greater the exposure, the greater the risk of

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disease." Green, *supra*, at 603. At a more granular level, the term describes "a relationship in which a change in amount, intensity, or duration of exposure to [a chemical] is associated with a change—either an increase or decrease—in risk." *McClain*, 401 F.3d at 1241–42 (citation and internal quotation marks omitted). This relationship is "the hallmark of basic toxicology" because "all substances potentially can be toxic." *Chapman*, 766 F.3d at 1307. Most "low dose exposures—even for many years—will have no consequence[s] at all." *McClain*, 401 F.3d at 1242 (citation and internal quotation marks omitted). This fact makes "[d]ose . . . the single most important factor to consider in evaluating whether an alleged exposure caused a specific adverse effect." *Id*. (citation and internal quotation marks omitted).

Background Risk of Disease. Background risk of disease simply means "the risk . . . the general public ha[s] of suffering the disease or injury that [a] plaintiff alleges without exposure to the drug or chemical in question." *Id.* at 1243. This risk assessment covers all "causes of a disease, whether known or unknown, excluding the drug or chemical in question." *Id.* The epidemiological and toxicological methods discussed focus on whether an association exists between a specific agent or disease. But without background risk as a baseline, determining whether an association is anything more than a coincidence becomes difficult, if not impossible. *Chapman*, 766 F.3d at 1307–08.

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#### B. The Deepwater Horizon Litigation

BP Exploration & Production, Inc. leased *Deepwater Horizon*, a deep-sea platform, to drill for oil off the Louisiana coast. On April 20, 2010, an exploratory well near the rig exploded. During the fire that followed, the platform sank, spewing millions of barrels of oil into the Gulf of Mexico. It took over 90,000 people and 7,000 vessels several months to clean up the spill.

In the years that followed, many clean-up workers and coastal residents sued BP Exploration & Production, Inc. and BP American Production Co. Exposure to crude oil and other chemicals from the spill, they alleged, caused various medical conditions. All personal-injury claims against BP were consolidated in the Eastern District of Louisiana as part of the Deepwater Horizon multidistrict litigation. In 2012, BP entered a settlement agreement with the personal-injury litigants that provided two avenues of recovery. Those diagnosed with a specified condition (like acute bronchitis) shortly after the spill (on or before April 16, 2012), could submit a claim for fixed compensation against the settlement pot. Those diagnosed after the cutoff date—with what the settlement agreement called "later-manifested physical conditions"—could file separate, individual tort suits against BP as part of the "Back-End Litigation" Option." Under the settlement's terms, these latent conditions must result from exposure to "oil, other hydrocarbons, and other substances released from" the spill or "dispersants and/or decontaminants used in connection with" response activities. And to recover for these conditions, backend plaintiffs must establish several

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elements, including the existence of a physical injury, "[t]he level and duration" of their "exposure," and that the injury was "legally caused" by that exposure.

Thousands of plaintiffs filed backend-litigation actions, Lester Jenkins and Dwight Siples Jr. among them. Both Jenkins and Siples joined the *Deepwater Horizon* clean-up efforts in 2010. Jenkins worked as a shoreline cleanup worker from June 2010 to January 2011, laboring 10–12 hours a day, five-to-six days a week. His cleanup efforts centered on Miramar Beach, where he spent his shift wading into the ocean to scoop tarballs out of the surf. Siples, for his part, decontaminated tractors, loaders, and other vehicles from July 2010 to September 2010.

Around 500 of the backend-litigation actions—including Siples's and Jenkins's—were transferred to the Northern District of Florida. The district court designated two bellwether groups and stayed all other proceedings. Because the "medical community" does not "widely accept[]" that "oil, dispersants, or any chemicals" associated with them "can cause common conditions" like "chronic sinusitis," the plaintiffs needed to prove general and specific causation. To save "time and expense" on "individual causation and damages questions," the district court bifurcated discovery and instructed the parties to address general causation "up front."

The first bellwether group chose Dr. Patricia Williams, a toxicologist, as their sole general-causation expert. *In re Deepwater Horizon BELO Cases*, No. 3:19-cv-963, 2020 WL 6689212, at \*1 (N.D.

Fla. Nov. 4, 2020). The district court excluded her expert testimony and granted judgment for BP. Id. at \*1. Williams's testimony, the court ruled, fell "woefully short of the Daubert and Rule 702 standards." Id. at \*12. Not only did Williams fail to establish a measure of exposure to the claimed toxins that could cause "the chronic medical conditions at issue," id. at \*15, but she also failed to reliably analyze the academic literature and performed a conclusory assessment of the Hill factors, id. at \*13–14. We upheld the decision because the district court made "no reversible error" in its "well-reasoned" opinion. In re Deepwater Horizon BELO Cases, No. 20-14544, 2022 WL 104243, at \*3 (11th Cir. 2022). Our decision aligned with the decisions of the Fifth Circuit about general causation in these BP backend suits. See Braggs v. BP Expl. & Prod., Inc., No. 23-30297, 2024 WL 863356, at \*3 (5th Cir. Feb. 29, 2024) (affirming exclusion of a general-causation expert because he "fail[ed] to identify the level of exposure capable of causing the alleged injuries"); *Prest v.* BP Expl. & Prod., Inc., No. 22-30779, 2023 WL 6518116, at \*3 (5th Cir. Oct. 5, 2023) ("[Plaintiff] does not cite any toxic tort cases where we have not required the plaintiff to show the harmful level of exposure to a chemical in the general population."); Byrd v. BP Expl. & Prod., Inc., No. 22-30654, 2023 WL 4046280, at \*2 (5th Cir. June 16, 2023) (same); see also Wunstell v. BP, P.L.C., Case No. 23-30859, 2024 WL 4100496, at \*2 (5th Cir. Sept. 6, 2024) (same).

The second group of bellwether cases included Jenkins's and Siples's. They both alleged that their clean-up work caused chronic sinusitis. They retained Dr. Michael Freeman and Dr. Gina Solomon as experts. Both experts' general-causation reports opined that

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a causal relationship existed between unspecified chemicals associated with the *Deepwater Horizon* oil spill and chronic sinusitis. Like Dr. Williams, neither Freeman nor Solomon identified the harmful level of exposure for crude oil, a dispersant, or the chemicals associated with them. BP cited that omission, among other issues, and moved to exclude both experts. BP also moved for summary judgment.

In a 79-page report, the magistrate judge recommended that the district court grant BP's motions. Although Solomon's and Freeman's reports varied in substance, the magistrate judge concluded that each expert's analysis suffered from the same basic flaws. The magistrate judge found that "to be reliable and helpful, a general causation expert in these [backend-litigation] cases must identify a harmful level at which a chemical in the oil or dispersant can cause" the chronic conditions "at issue here." Both experts, the magistrate judge concluded, failed to pass this threshold test: neither identified a minimum level of exposure at which crude oil, its dispersants, or the chemicals in them are hazardous to human beings. The experts' studies also did not identify a statistically significant association between the chronic conditions and exposure to crude oil. And both experts failed to assess the various studies' limitations. Finally, the experts failed to "meaningfully consider" whether the Hill factors supported a causal inference between crude oil and the chronic conditions.

The district court determined that the magistrate judge's report and recommendation "[was] correct as a matter of law" and

adopted it in full. The district court first affirmed the primary principle grounding the magistrate judge's decision: a toxic-tort plaintiff in these backend litigation actions must "demonstrate the levels of exposure that are hazardous to human beings generally" to prove general causation. Second, the district court rejected plaintiffs' position, advanced "without legal support," that it should "focus on the complex toxic *mixture* of chemicals from crude oil spills, rather than requiring the identification of a particular chemical component in the general causation analysis." As for the magistrate judge's other findings, the district court concluded that the judge's report "provided a detailed evaluation of each expert report . . . and accurately identified flaws in the underlying studies that the experts acknowledged existed, but which they did not bother to analyze in making their ultimate general causation conclusions." Because neither Jenkins nor Siples presented "reliable expert general causation testimony," the district court granted BP's summary judgment motions.

#### II. STANDARD OF REVIEW

We review a summary judgment *de novo*. *Rink v. Cheminova*, *Inc.*, 400 F.3d 1286, 1294 (11th Cir. 2005).

We review the exclusion of expert testimony for abuse of discretion. *Chapman*, 766 F.3d at 1305. This standard "places a heavy thumb—really a thumb and a finger or two—on the district court's side of the scale." *United States v. Pon*, 963 F.3d 1207, 1219 (11th Cir. 2020) (citation and internal quotation marks omitted). These scales tip "with even greater force" in favor of the district

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court for "Daubert issues in particular" because it is "uniquely entrusted" with "the task of evaluating the reliability of expert testimony." United States v. Brown, 415 F.3d 1257, 1266 (11th Cir. 2005) (citation and internal quotation marks omitted). So the question is not whether we would make the same call as the district court in the first instance. United States v. Frazier, 387 F.3d 1244, 1259 (11th Cir. 2004) (en banc) (citation and internal quotation marks omitted). Instead, we give the district court "considerable leeway," Brown at 1266 (citation and internal quotation marks omitted), and ask whether its decision is "in the ballpark of permissible outcomes." United States v. Irey, 612 F.3d 1160, 1189 (11th Cir. 2010) (en banc).

Considerable leeway "is not the same thing as abdicating appellate responsibility." *Brown*, 415 F.3d at 1266. Under the abuse of discretion standard, we defer to the district judge's decision unless it is "manifestly erroneous." *Chapman*, 766 F.3d at 1305 (citation and internal quotation marks omitted). The exclusion or admission of expert evidence is manifestly erroneous if the district court misapplies the law, makes a "clearly erroneous" factual finding, or follows improper procedures. *Seamon v. Remington Arms Co., LLC*, 813 F.3d 983, 987 (11th Cir. 2016) (citation and internal quotation marks omitted). "[T]he abuse of discretion standard allows a range of choice for the district court, so long as that choice does not

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constitute a clear error of judgment." *Frazier*, 387 F.3d at 1259 (citation and internal quotation marks omitted).

#### III. DISCUSSION

Jenkins and Siples challenge the exclusion of their experts, Solomon and Freeman, and the summary judgment in favor of BP. Because they bring a toxic-tort action—one where the medical community has not recognized the toxicity of the oil and dispersants used to clean up the *Deepwater Horizon* spill—they must prove general causation through admissible, reliable expert testimony. *McClain*, 401 F.3d at 1239. We must affirm the grant of summary judgment if Jenkins and Siples "fail[] to make a sufficient showing on [this] essential element of [their] case." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986).

Under Federal Rule of Evidence 702, expert evidence is admissible if the expert is qualified, the expert's methodology reaches a "sufficiently reliable" conclusion under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and the expert's testimony will help the factfinder determine a fact issue through the application of scientific, technical, or other specialized knowledge. *United States v. Markovich*, 95 F.4th 1367, 1377 (11th Cir. 2024). Under *Daubert*, district courts act as "gatekeepers," admitting testimony only if it is reliable and relevant. *Rink*, 400 F.3d at 1291 (quoting *Daubert*, 509 U.S. at 589). This gatekeeping role requires district courts to assess "whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue."

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*Kilpatrick v. Breg, Inc.*, 613 F.3d 1329, 1335 (11th Cir. 2010) (citation and internal quotation marks omitted).

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Jenkins and Siples argue that the district court overstepped this gatekeeping role when it excluded their experts. More specifically, they contend that it incorrectly applied our precedent when it concluded that a "general causation expert in these [backend-litigation] cases must identify a harmful level at which a chemical" could cause the harm alleged. In Jenkins and Siples's view, a threshold level of toxin is "only relevant to *specific* causation." They also argue that no principle of epidemiology—the primary methodology used by their experts—"requires a general causation analysis to include a threshold dose."

Our precedents foreclose Jenkins and Siples's argument about general causation. Starting with *McClain*, we held that a toxic-tort plaintiff "must demonstrate the levels of exposure" to the alleged toxin "that are hazardous to human beings generally." 401 F.3d at 1241 (citation and internal quotation marks omitted). There, we affirmed the exclusion of a general-causation expert who "offered no testimony about the dose of" the alleged toxin "required to injure Plaintiffs or anyone else" and "could not say how much is too much." *Id.* Because the expert did not "provide any opinions" about the "level of exposure at which [the alleged toxin] causes harm," he did "not follow the basic methodology that scientists use to determine causation." *Id.* at 1241–42. Likewise, in *Chapman*, we affirmed the exclusion of general-causation experts who failed to establish that the alleged toxin increased the risk of disease.

766 F.3d at 1308. We specifically focused on the expert's failure to prove "how much" of the alleged toxin "must be used for how long to increase the risk." *Id.* at 1307. And in *Taylor v. Mentor Worldwide LLC*, we reiterated that, under *McClain*, "a plaintiff must demonstrate . . . the level of exposure to the allegedly harmful chemical that is hazardous to a human being." 940 F.3d 582, 595 (11th Cir. 2019) (citation omitted).

Decisions from other circuits point in the same direction. The Fifth Circuit has long held that "[s]cientific knowledge of the harmful level of exposure to a chemical" (general causation) "plus knowledge that the plaintiff was exposed to such quantities" (specific causation) "are minimal facts necessary to sustain the plaintiff's burden in a toxic tort case." *Allen v. Penn. Eng'g Corp.*, 102 F.3d 194, 199 (5th Cir. 1996). So have the Fourth, Tenth, and Eighth Circuits. *See Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 263 (4th Cir. 1999), *Mitchell v. Gencorp Inc.*, 165 F.3d 778, 781 (10th Cir. 1999); *Wright v. Willamette Indus., Inc.*, 91 F.3d 1105, 1106 (8th Cir. 1996).

The district court did not abuse its discretion when it required the experts to identify a "toxin" and prove it "[was] harmful above a particular threshold" and excluded them because they failed to do so. Instead, it applied general-causation principles drawn directly from our precedents, aligned with those of other circuits, and consistent with the reasoning of every other decision in *Deepwater Horizon* backend-litigation suits. This holding is hardly the kind of misapplication of precedent that chalks up to error, much less a manifest one.

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Jenkins and Siples contend that proof of some threshold level of exposure is "only relevant to *specific* causation." In support, they argue that *McClain* concerned only "toxicological principles or specific causation." But this reading turns *McClain* on its head.

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The passages that Jenkins and Siples quote address both general and specific causation. McClain's first "minimal fact[]"—"[s]cientific knowledge of the harmful level of exposure to a chemical"—relates to general causation: "whether an agent increases the incidence of disease in a group." 401 F.3d at 1239, 1241 (citations and internal quotation marks omitted). The other "minimal fact[]"—"knowledge that plaintiff was exposed to such quantities"—relates to specific causation. Id. at 1241 (citation and internal quotation marks omitted). And in McClain, we applied the general-causation requirement to the plaintiffs' general-causation expert. Id. at 1237, 1241. We also followed the same route in Chapman. 766 F.3d at 1307 (affirming exclusion where neither of the plaintiffs' general-causation experts "determine[d] how much" of an alleged toxic agent "must be used for how long to increase the risk of' the disease).

Jenkins and Siples try to dodge this straightforward reading by asserting that "[h]ow much of an agent is sufficient to cause harm" goes to "whether the substance caused the plaintiff's *specific* injury." But this argument confuses the issue. A plaintiff's exposure to the threshold dose of a toxin is relevant to specific causation. Yet we also ask, under our general-causation framework, whether a harmful level of the toxin exists in the first place.

Jenkins and Siples also argue that the district court erred when it required their experts "to analyze general causation for specific chemicals contained in crude oil or dispersants," rather than for oil or dispersants more generally. But neither Solomon nor Freeman established a harmful exposure level for oil or dispersants generally—much less a harmful exposure level for a specific chemical or compound in them. The latter (specific chemicals or compounds) nests like a Matryoshka doll inside the former (oil or dispersants generally). The district court did not err when it excluded the experts because they identified no harmful exposure level for any substance. That exclusion was appropriate whether the district court focused on specific chemicals or on oil and dispersants more broadly.

Last, Jenkins and Siples argue that *McClain* applies only to toxicology evidence, not to the epidemiology evidence offered by their experts. But threshold level of exposure aside, the district court did not abuse its discretion when it excluded Solomon and Freeman for myriad other reasons.

Although Jenkins and Siples contend that the district court excluded Solomon "based on findings that are factually inaccurate" and "contrary" to the "methodology Dr. Solomon followed," the meticulous and well-reasoned decision of the district court belies these arguments. The district court did not err when it ruled Solomon's opinions were "neither reliable nor helpful" because she "failed to identify a statistically significant association in the literature, failed to meaningfully critique the Rusiecki 2022 study, or any

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other epidemiological study, failed to provide more than a hasty discussion of the Bradford Hill factors, failed to discuss the doseresponse relationship or background risk of disease, and failed to identify a harmful dose."

Each of these findings easily survives our abuse-of-discretion review. To start, the district court did not err when it found that Solomon's cited studies failed to support her causation opinion. One of Solomon's studies focused on acute rather than chronic conditions. Another assessed a different disease, asthma. As for the Rusiecki study, Solomon ignored its limitations, never mentioning its internal inconsistencies and the potential errors introduced by the subjects' self-reporting. The district court also did not err when it discarded Solomon's cursory discussion of the Hill factors: she addressed only three of the nine factors in a few brief sentences. And it did not err when it found that Solomon failed to discuss either the dose-response relationship or the background risk of disease.

The same holds true for Freeman. Siples and Jenkins argue that the district court "simply disagreed with Dr. Freeman's interpretation of the epidemiological evidence and his application of the Bradford Hill guidelines." And in the same vein, they accuse the district court of "improperly review[ing] the correctness of Dr. Freeman's conclusions rather than the reliability of his principles and methods." Again, even a brief glance at the decision by the district court refutes this position.

Like Solomon, Freeman disregarded limitations in his cited studies—limitations that the studies' own authors stressed. For instance, Freeman relied on a cross-sectional study about acute rather than chronic conditions to support his general-causation opinion, even though the study's authors stated that their conclusions "were not intended to describe or investigate potential long-term or chronic health effects." The district court found that another study suffered from clear "selection bias," which Freeman "acknowledged" but "failed to address." And the Rusiecki Study found no statistically significant association between exposure to oil and chronic sinusitis except for a single subgroup where the statistical significance disappeared once the authors eliminated smokers. In the light of these limitations, the district court did not err when it found that the "studies [Freeman] relied on" did not "provide an adequate basis for his general causation opinion." And this finding questioned Freeman's methodological failings, not his conclusions.

Nor did the district court err when it excluded Freeman because of his "cursory and superficial" Hill-factor analysis. Unlike Solomon, Freeman at least discussed most of the factors, in a sentence or two for each. But his assessments missed the mark. And he offered little to no explanation or support for conclusory statements about dose-response relationships or "chain of causation between the acute and chronic symptoms." No abuse of discretion occurred when the district court concluded that his "analysis d[id] not represent a reliable application" of the Hill factors.

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The district court did not err when it found that Solomon and Freeman failed to support their opinions with epidemiology, dose-response relationship, or background risk of disease. *See Chapman*, 766 F.3d at 1308. So—even setting the threshold dose aside—the district court did not abuse its discretion when it excluded their testimony and granted summary judgment to BP.

### **IV. CONCLUSION**

We AFFIRM the judgment in favor of BP.